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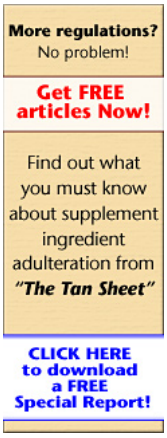

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MONDAY, MARCH 16, 2009

FDA Commish To Employees: Keep Quiet or Else!

Frank Torti, the acting FDA commissioner, has an important message for all agency employees--you won't make a peep if you know what's good for you.

In an unusual memo distributed last Friday afternoon, Torti ensured the agency is committed to transparency and "the principles of open government." But after dispensing with the obligatory qualifier, he then went on to warn FDA employees the agency "must comply with its obligations to keep certain information in its possession confidential."

He then writes those obligations are spelled out in the Food, Drug, and Cosmetic Act, the Freedom of Information Act (FOIA), the Trade Secrets Act, and the Privacy Act, as well as FDA regulations. But if agency employees violate these provisions, they may face disciplinary sanctions, criminal liability and the FDA could be sued for damages.

Torti cites five sweeping categories of info that must be kept under wraps: trade secrets; confidential commercial info; personal privacy data; law enforcement records and privileged intra-agency and inter-agency documents, such as emails, memos and letters between between FDA employees. This last category can be a veritable treasure trove, however, because it can include opinions issued by FDA employees and materials prepared in connection with litigation – the sort of stuff that makes a good headline.

The missive, which an FDA spokeswoman tells us speaks for itself, may have its roots in a recent pair of embarrassing episodes that stemmed from the discussion or release of what FDA officials may view as privileged info. Earlier this year, nine FDA scientists wrote President Obama's transition team that the review process for medical devices was 'corrupted and distorted by agency managers.'

An example surfaced last week in a report in The Wall Street Journal, which detailed how a lobbying campaign overcame internal dissent among FDA staffers, who objected to the approval of a ReGen Biologics device for knee injuries. Former FDA commish Andy von Eschenbach acknowledged the affair was handled poorly.

And last month, the FDA removed Sanjay Kaul, a well-known cardiologist at the Cedars-Sinai Heart Institute in Los Angeles, from a

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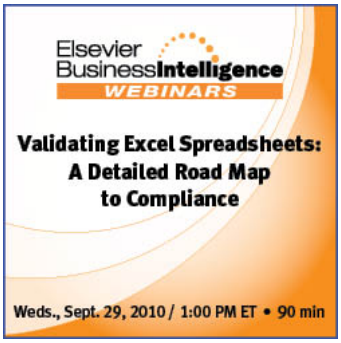

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